

## **REMARKS**

In accordance with the above amendments, claims 183-184, 186, 189-194, 196, 199-205 and 208-211 have been amended. Claims 212-257 have been withdrawn as being directed to a non-elected invention. Claims 183-186, 189-196, 199-205 and 208-211 remain under consideration in the present application. No claim has been allowed.

### **Claim Rejections 35 USC § 112**

In the present Action, all of the claims under consideration remain rejected under 35 USC § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner has retained a rejection based on the conclusion that the application only exemplifies transgenic mice and from that it is not possible to extrapolate a phenotype from that to other mammal species. This rejection is again traversed for reasons of record and, in addition, applicants submit that they are in the process of assimilating additional supporting evidence based on work conducted using the method of the invention in an additional species. In this regard, in an RCE, applicants have requested a suspension of action in the subject application for three months in order that they may submit such additional evidence to support their position.

It is further noted that the Examiner does admit and agree that the instant specification teaches a method of producing

transgenic progeny, but has pointed out that the injected non-human mammal would be a founder or host animal and not transgenic, as required by certain of the claims. Accordingly, the claims have been amended to specifically point out that the injected mammals are host or founder animals and that only the germ cells are transgenic. The progeny of these animals, however, are transgenic.

Withdrawal of the previous rejections under 35 USC § 112, second paragraph, based on indefiniteness, is gratefully acknowledged.

#### **Claim Rejections 35 USC § 102**

The claims under examination remain rejected under 35 USC § 102(e) as being anticipated by Bryant et al (USPN 6,156,952, dated December 5, 2000, with an effective filing date of April 19, 1998). Support for the claims has not been extended to U.S. Provisional Application No. 60/065,825, dated November 14, 1997, by the Examiner. The Examiner has rejected the claims based on the Bryant et al reference describing non-human animals comprising lentiviral and a transgene material in their genome. This rejection is respectfully traversed.

Without conceding that the reference is of good date, a reading of Bryant et al indicates that they are studying expression activity of different portions of the HIV genome as a method for understanding the virus and its mode of action.

Bryant et al are generating transgenic mice by using the classic method of injection of the gene construct into the fertilized egg as opposed to the transduction of male germ cells as required by the claims of the present invention. Therefore, the method of Bryant et al is different from that of the present invention and the immediate product of the process is also different, as the product of the current invention is a transduced male germ cell that may then be subsequently used to produce a transgenic animal.

In addition, the present claims remain rejected under 35 USC § 102(b) as being anticipated by Leonard et al (AIDS Res Hum Retroviruses. 1989; 5(4):421-30). The Examiner has further indicated that Leonard et al teach transgenic mice containing HIV LTR linked to a bacterial gene and the making of founder transgenic mice with non-transgenic mice arguing that this would meet the structural limitations of the present claims. This rejection is also respectfully traversed.

It is noted that Leonard et al does report the use of a construct having a part of the HIV genome, namely, the LTR region, and linking it to a bacterial-derived reporter gene. As was the case with Bryant et al, however, Leonard et al produced transgenic mice expressing the construct by conventional methods of transgenesis, namely, injection of the gene into a fertilized egg. The method does not require the transduction of a male germ

cell using a viral construct. The transduced male germ cell of the present invention is the direct product of the new process with a transgenic animal being subsequently produced and, as such, the product of the process is clearly different.

Because the cited references do not disclose all of the elements and limitations of the present claims, the claims cannot be anticipated by them and reconsideration and withdrawal of these rejections is respectfully requested.

It is gratefully acknowledged that certain earlier rejections under 35 USC § 102 have been withdrawn.

Respectfully submitted,

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A handwritten signature in dark ink, appearing to read "C. G. Mersereau", is written over the typed name.

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